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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,079	06/22/2001	Signe Erickson Varner	55821 (71699)	6574
21874	7590	10/20/2004	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			DESANTO, MATTHEW F	
			ART UNIT	PAPER NUMBER
			3763	
DATE MAILED: 10/20/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/888,079

Applicant(s)

VARNER ET AL.

Examiner

Matthew F DeSanto

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2004.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 23-76 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 23-76 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/19/04.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
2. Claims 23, 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 23 and 60 are indefinite and unclear to the examiner because the claims use the term “the device” and there is no limitation in the claim that describes the device. Is the device the cannula or a separate structural element?

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 23-30,32,33-40,42-44,47-52,54,55,58-65,67-69, and 72-76 are rejected under 35 U.S.C. 102(e) as being anticipated by Paques et al. (US Pub 2003/0171722).

Paques et al. discloses a method for treating an eye with a device comprising a piercing member (4) with an outer diameter less than 25 gage (0053) allowing the puncture location to self-seal and having a flexible plastic tube therein (0087) to administer a therapeutic substance to the eye. The device is used to treat conditions such as vascular occlusion (0039) by advancing the device transconjunctively and

Art Unit: 3763

piercing the sclera of the eye and delivering a therapeutic agent subretinally (Figure 1, 2 and paragraph [0105]-[0113]).

*Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31,45,46,56,57,70,71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paques et al. in view of del Cerro et al (USPN 5,409,457).

Paques et al., as described above, teaches a device for subretinal delivery of a therapeutic agent wherein the device has an outer piercing member and an inner cannula, but fails to teach withdrawal of fluid from the eye.

Del Cerro et al. teaches a device comprising a tip for penetrating the subretinal region of the eye to deliver a therapeutic agent or withdraw fluid from the eye (column 4, line 31).

It would have been obvious to one skilled in the art at the time of the invention to withdraw fluid from the eye in order to reduce the pressure in the eye, as well as to deliver therapeutic fluid to treat the disease or injury both actions possible with the syringe connected to the device of Paques.

7. Claims 41, 53, 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paques et al. in view of Bowman et al. (USPN 6,378,526)

Paques et al., as described above, teaches a device for subretinal delivery of a therapeutic agent wherein the device has an outer piercing member and an inner cannula, but fails to teach the delivery of steroids.

Bowman et al., teaches a device for delivery of a therapeutic agent such as steroids, genetic material, or pharmaceuticals to the eye.

It would have been obvious to one skilled in the art at the time of the invention to deliver agents such as steroids to the eye depending on the needs of the patient.

*Response to Arguments*

8. Applicant's arguments filed 8/10/04 have been fully considered but they are not persuasive.

9. With regards to a method of inserting a device into the eye by piercing the eye with the needle and then followed by inserting the piercing member and the cannula into the eye is taught in Paques paragraphs [0105-0113].

10. With regards to the piercing member creating self-sealing slits in the eyes, the examiner believes that the prior art is inherently capable of creating self-sealing slits, since there is no other special structure or method limitations claims that would produce a different slit, therefore the examiner determines that this prior art would create the same slits and thus from self-sealing slits.

*Conclusion*

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 3763

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (703) 308-2698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew DeSanto  
Art Unit 3763  
October 18, 2004



**NICHOLAS D. LUCCHESI**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 3700**